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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

RE: 21 CFR Part 589
Docket No. 2004N-0264
RIN 0910-AF46

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

RE: 9FR Parts 50 through 85
Docket No. 04-047-1
RIN 0579-AB86

Food Safety Inspection Service

RE: 9 CFR Parts 309, 310, 311, 318 and 319
Docket No. 04-021 ANPR
RIN 0583-AC88

1. Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?

Yes, but should be a representation from not only the scientific field but renderers, cattle producers, packers and other stakeholders who are involved in reducing the risks of proliferating BSE in the U.S. They should study the cost/benefit ratio of new regulations.

2. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?

Has FDA and FSIS ever studied the level of infectivity in distal ileum or small intestine after proper rendering? After attending many BSE seminars in Europe and the U.S. since 1988, there seems to be a consensus that the highest level of infectivity in the small intestine of a BSE animal and the tonsils of cattle under 30 months of age is a maximum of 10^2 ID₅₀/g. In the only experiment where specified risk materials (SRMs) were rendered¹, all U.S. rendering systems (except one, which couldn't be duplicated) reduced infectivity by a minimum of 2 logs. FSIS

¹ D.M. Taylor, S.L. Woodgate, M.J. Atkinson (1995) "Inactivation of the Bovine Spongiform Encephalopathy Agent by Rendering Procedures," *The Veterinary Record*, ppgs. 605-610.

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could remove the small intestine, but there is no scientific reason to include the small intestine as a SRM to be disposed of in an expensive, dedicated disposal plant if it is properly rendered. I recommend quick-testing all animals over 30 months of age..

Does FSIS propose to remove small intestine of veal calves? Has FDA and USDA considered the thousands of dairy and beef calves that die before they are six months of age? Why remove the small intestines of these animals? The small intestine from cattle under 30 months of age, including deadstock, should be rendered and fed to poultry, swine and pet food as meat and bone meal (MBM).

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

I have no U.S. scientific data to refute the IRT statement, and the IRT does not have U.S. scientific data to back up their recommendations. They are using the European model for the U.S. I have recently visited farms in the U.K. and Ireland, and their livestock husbandry practices are still similar to U.S. livestock production when I was a large animal veterinarian in Missouri from 1951-56. The U.S. has changed, Europe has not.

As far as I know from visiting with renderers, packers, blenders and others who sell MBM on a daily basis, no feed mill that produces ruminant feeds purchase prohibited MBM. The exceptions are modern, large mills that have completely separate lines and bins. The FDA field inspectors can verify this statement. A California renderer supplied 17 mills with prohibited material that was used in poultry feed. The mills also produced cattle feed and flushed the system when switching from poultry to cattle feed. Due to the risk of cross-contamination, there is only one poultry mill purchasing prohibited MBM today. This is true in 49 states (Hawaii does not have an active feed mill). Until recently, under FDA inspection, a few renderers had separate lines except for grinding and screening. They flushed the equipment, but most have discontinued the practice and have allocated raw material to either a prohibited plant or non-prohibited plant. Again, FDA field personnel can verify this statement.

Regarding cross-contamination on farms, livestock farms concentrate on one animal specie. Why would a dairyman purchase swine feed and feed it to his milking cows? It is not formulated for dairy cows, and they would go off-feed and milk production would be reduced. Today, you raise poultry, or swine, or dairy cattle, or raise beef cattle. If you did have two species on a farm, the feed would be purchased as bulk feed and placed in a separate feed bin in a different area of the facility. The "old days" are gone. The U.S. is not Europe, and the IRT was off track with their remarks. Single specie production has been the trend for the past 40 years in the U.S. Livestock producers today purchase their milk at a supermarket (no more milk cows on the farm).

Feeding errors on the farm - U.S. farms mix feed for one species only. Dairy cows, swine or turkey feed.

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

No. We have never had an indigenous case of BSE in the U.S., and we have been feeding SRMs to livestock since 1909. I believe we will have to remove SRMs from human food to recapture our foreign edible markets and to satisfy the U.S. public. There is no need to remove SRMs from animal feed unless a customer requests it. What has changed in U.S. feeding practices before 12-23-03 versus today that increases the risk of BSE proliferation? We have not found BSE in our surveillance testing. Why create a two-tier rendering system at a staggering cost if it is not necessary? Renderers can charge more for picking up deads, downers and SRMs if they are not allowed in feed, but more deads will be pulled to the trees, back fence row, etc. and their parts will be scattered all over the county. It will increase the spread of animal diseases, and composting and burying is not the answer. How do we dispose of SRMs without a subsidy? The major tonnage will come from cow kills, deads and downers. We can build SRM plants, but costs will be extremely high to the renderer, plus burning rendered products in special boilers. MBM has a low BTU level and another fuel will have to be used with MBM. Can use tallow in biodiesel or burn with MBM. If we are going to use European model, then why don't we subsidize the renderer as they do in Europe? Large renderers may survive, but small deadstock renderers will be closed.

Why not continue feeding SRMs in prohibited MBM until our enhanced testing program has reached at least 150,000 head. What has changed, except for an imported BSE cow? The 1997 ban is working, with no major hardship on any part of the animal industry.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

None. Can detect some SRMs in raw material, but not rendered product. This is one reason we should not change anything. Some small packers are removing SRMs now for renderers who are marketing their MBM as SRM-free to pet food companies. They are selling the SRM MBM as an ingredient in poultry and swine feed.

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM free rendered material and material rendered from SRMs?

Labeling and adding charcoal to SRM product. The dedicated SRM plants will have to be inspected to determine how they are processing the SRMs. No one will purchase the SRM MBM for feed at market prices. The FDA knows that U.S. renderers don't cheat; we follow your regulations to the letter. It will be an expensive project to destroy SRMs. This is why renderers who operate dedicated plants will have to have government grants to properly dispose of SRMs, deads, downers, etc. An alternative is, the raw material not allowed in feed (deads, downers,

SRMs) be transported to approved landfills. This is no solution, because if we picked up a BSE animal, does the FDA approve of its disposal in a landfill?

Why don't we exempt deads under 30 months of age and have USDA quick-test all the deads over 30 months of age? Building a cooler is more economical than building a dedicated rendering plant. APHIS, USDA could train competent supervisors to take samples daily, not twice a week.

How will renderers be able to pick up small or medium sized slaughtering plants if SRMs have to be transported in a dedicated truck? Should small slaughterers dispose of SRMs in a dumpster? The FDA and USDA may not approve of this practice. There are too many problems, in a large country such as the U.S., to properly dispose of SRMs in rural areas. In my opinion, the FDA should not change anything. SRMs could be frozen and picked up by renderer once a week in dedicated truck, but it would be very expensive.

7. What would be the economic and environmental impacts of prohibiting SRMS from use in all animal feed?

It is not just SRMs involved, but deadstock and downers, as well. Renderers would charge packers a very high fee to transport SRMs in dedicated vehicles to dedicated plants. Price of beef overall would increase, with cow meat having a significant increase. Small slaughterers could build a special freezer and freeze SRM's so that renderer could pick-up once a week in dedicated vehicle and transport to dedicated plant. Very expensive. I think it would put many slaughterers out of business. FDA would observe rotten deads, half-buried, half-composted animals in pastures. It would be more economical for livestock producer to haul deads (dedicated truck) to a landfill. Does FDA prefer this or to have animals tested at rendering plant? Most producers will let them rot in the field if pick-up costs increase. Keeping SRMs and offal from cattle over 30 months of age in feed is the logical answer.

Fats and Proteins Research Foundation (FPRF) are allocating most of their research dollars to developing "other than feed" uses for MBM. If FDA does not allow poultry or swine MBM in cattle feed, pork and poultry prices will increase. Should we remove pork and poultry products from ruminant feed because the IRT doesn't understand U.S. livestock and poultry production? Should the U.S. animal industry be penalized because the Europeans cheated until 1996?

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

So low it would be hard to measure. Small children may put a dog or cat food crumble in their mouths occasionally, but I have never heard of a child becoming ill. No, it is not a relevant concern for removing SRMs from all animal feed. SRMs have been in dry pet food since the early 1940s, and in canned pet food since 1928. I have heard of families that ate canned dog food during the Depression, and I never heard of anyone becoming ill.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross-contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage and transportation? If so, what would be the scientific basis for such a prohibition?

The Fats and Proteins Research Foundation (FPRF) is funding a study, "Development of Monoclonal Antibody Based Immunoassay for Rapid Detection of Ovine and Other Specific Species Tissue in Rendered Products," with Dr. Pegg Hsieh at Florida State University². Attached is an update of Dr. Hsieh's work. Other private companies are also working on the same objectives as this study. We will soon have a test for ruminant protein.

As I mentioned in question 3, there is little or no cross-contamination taking place in rendering plants, feed mills or on livestock-producing units. Because of the nature of the rendering industry, dedicated storage and transportation is critical, and completely separate rendering lines are necessary. Today, renderers either produce prohibited or non-prohibited product. If SRMs have to be destroyed, we need dedicated plants, but if they could be part of prohibited MBM, there would be no problem. I have suggested the latter approach, to continue on as we are now until we receive results of enhanced testing programs.

The most scientific data available is:

- We have been feeding SRMs since 1909
- No indigenous cases of BSE and
- No BSE found in high-risk cattle in the USDA surveillance program since 1986-87

There is no scientific basis for prohibition. To recapture our overseas edible beef market, we may have to remove SRMs whether it is necessary or not, but don't change a thing in the inedible sector.

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage and transportation?

If SRMs, deads and downers have to be destroyed, then the economic impact on renderers will be horrendous. As mentioned earlier, the cost of procuring SRMs in dedicated truckings, rendering SRMs, and either using alkaline digestion, incineration or purchasing a boiler that would burn MBM would be costly, and would be reflected in higher beef prices, especially cow meat. More than likely, per cwt. price of cows would decline. A separate facility would have to be built to house the equipment. If deads and downers are included, there would be a significant effect on the environment. The costs to pick-up would escalate, resulting in rotten animals being

² Dr. Peggy Hsieh, Florida State University, "Development of Monoclonal Antibody Based Immunoassay for Rapid Detection of Ovine and Other Specific Species Tissue in Rendered Products," Research Project June 1, 2003 – May 31, 2005, funded by Fats and Proteins Research Foundation.

scattered all over the countryside, especially in waterways. I would think the objective would be to pick up more deads, not less.

11. What information, especially scientific data, is available to demonstrate that cleanout would provide adequate protection against cross-contamination if SRMs are excluded from all animal feed?

I believe the FDA has extensive files on the effectiveness of clean out. Renderers who flushed their grinding, screening and conveyors under FDA inspection were given high marks when separating prohibited from non-prohibited product. It would save much money if SRMs could be processed in one rendering plant by flushing. **WHAT WOULD YOU DO WITH SRM MBM STORED IN DEDICATED SILO AND TALLOW IN DEDICATED STORAGE TANK?** We might be able to use some SRM MBM in concrete at a very low price. If we could develop a test for SRMs (nerve tissue) we could determine if flushing was effective. Wouldn't it be more economical for renderers and livestock producers to quick-test daily all deads and downers over 30 months of age for a few years? If all test results are negative, we can forget SRMs, dedicated facilities, etc. It would not have a severe impact on cow prices, rendering operations, etc. Renderers and packers could either test and hold in cooler, or store each day's production of MBM in separate silo until test results were received (24 hours). This would complement the present enhanced testing program. My real feeling is to do nothing until we have results of enhanced testing program.

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

There is no scientific data. The IRT is again using the European model to propose rules for North American animal husbandry operations. We are light-years apart on our husbandry practices. Poultry feed products are produced in dedicated non-prohibited facilities. Europe has many small slaughtering facilities that slaughter a few of all species. IRT believes the U.S. is the same. The majority of U.S. slaughterers who kill multi-species are kosher plants and small locker plants. Their raw material is considered prohibited material. Where does the cross-contamination come from at Tyson, American Proteins and other large poultry integrators that slaughter only poultry? Or for Cargill, Swift, IBP pork plants that slaughter only hogs? Independent renderers produce mixed specie (prohibited) MBM. There are a few that have separate lines and have been inspected by FDA many times. FDA could rule that all rendering plants produce either all prohibited or non-prohibited material. I believe as consolidation continues in the industry, this action will not be necessary.

When we analyze the ruminant MBM in poultry intestine's lumen, we must consider that MBM inclusion level in poultry, as well as swine feed, is 10% of the rations. Most of the MBM in lumen has been digested at the time of slaughter. Not all animal proteins in swine and poultry rations are of ruminant origin. Many poultry integrators feed their birds feed-grade PBPM, pork meal and feather meal. If animal proteins are used in ruminant rations, it is usually pork blood meal. There may be ½ pound of poultry or pork MBM, but it is rare. The odds of a ruminant animal receiving more than a gram of undigested mixed-specie MBM are very high. This

recommendation is ridiculous when directed toward a country (the U.S.) that has not had an indigenous case of BSE.

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

If SRMs are removed from animal feed, there is no need to prohibit all mammalian and avian MBM from ruminant feeds or amend the existing feed rule. I think this question misses the point; pork and avian MBM are no-risk MBM. The rendering industry can live with the ruminant-to-ruminant ban. Don't change anything. If we find BSE in our enhanced testing program, then that is when we should consider changing the rules.

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

It would mean more animal proteins competing in a smaller market. Pork MBM has been selling at a \$30-\$80 premium over ruminant MBM for the past 6 months. That premium would be lost, and since avian MBM does not have a significant share of animal proteins used in ruminant rations, it would have only a minor decline. Pork blood meal sells for a \$500 premium over ruminant blood meal. This premium would be lost, and place pressure on ruminant blood meal. Again, more product chasing a smaller market. The drop value to pork and cattle packers would decline, and would be reflected in lower live animal prices. Renderers' end products prices would drop, which would necessitate charging more for picking up animal by-products. There would be a significant impact on all of animal agriculture. If the FDA would grant a 30-day extension, we could furnish more exact figures.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

I know of no scientific risk in using ruminant blood meal in ruminant rations. Much of the adverse publicity was based on the death of an English patient who received a transfusion from a person suffering from a BSE-like disease. Health Secretary John Reid cautioned Parliament it was not possible to determine whether the transfusion recipient contracted the fatal brain-wasting illness through the blood transfer, or whether the two people were independently infected.

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

None.

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

No.

18. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

Bovine and porcine blood meal would be selling close to same prices, bovine blood meal moving up, and porcine blood meal coming down. It is my opinion that porcine blood meal would bring approximately a \$100 to \$150 per ton premium over bovine blood meal, due to the adverse publicity that has been associated with past regulations and the perception by some feed mills that livestock producers would prefer porcine blood meal. Others who are more familiar with plate waste and poultry litter will comment on this subject, but plate waste going into feed would now go to landfill at an additional cost, and there would be a cost to dispose of poultry litter in an environmentally friendly manner.³

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

This is the standard set by OIE. Several years ago, the National Renderers Association (NRA) entered into negotiations with the E.U. for the continued export of U.S. tallow to Europe. Scientists from European chemical companies who produce glycerine and fatty acids from tallow agreed with our U.S. consultants, that the extreme temperatures and pressure associated with the treatment of tallow for the production of fatty acids for commercial use, was sufficient to destroy the BSE agent.

If a dairy producer added tallow to his dairy ration so each cow received one pound of tallow per day, and the tallow contained 0.15 impurities, the cattle would receive less than 0.15 of a pound of rendered protein per day, and the impurities could contain filter clay or other inert products used to treat the tallow. U.S. should use AOCS procedures to test for impurities.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

All except decomposed animals. As mentioned earlier, there is no more risk of an animal under 30 months of age for slaughter than for deads and downers. I suggest we quick-test all cattle over 30 months of age, which will eliminate the SRM issue. It is easier to build a cooler than a dedicated SRM disposal plant. A Japanese panel of experts in a report⁴ stated that younger cows do not accumulate enough abnormal prions to be detected by current test. If we render all SRMs of cattle under 30 months of age, and cattle over 30 months of age that test negative, the SRM MBM, as well as other tissue MBM, would be safe to feed to swine, poultry and pets.

³ North American Rendering Industry's response to the Report of IRT, addressed to Dr. Lester Crawford, dated 02/26/04.

⁴ Pro-MED-mail. Yahoo News, 16 July 2004. "Japan Says Cattle Under 30 Months May Not Be a BSE Risk."

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

There are no methods if all raw materials are mixed and rendered.

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Most renderers who depend on deadstock as the principle or substantial portion of their raw material would close and livestock producers would have to bury, compost or incinerate their deads. None of the above is satisfactory, as they cannot bury in winter months, and are too busy to bury in summer. Most producers eventually give up composting, as it is labor intensive. Incineration is very expensive, so the answer is to pull the animals into the brush or creek and let it rot. They are great meals for dogs, coyotes, buzzards, etc. It would have a severe environmental impact. Many would go to landfills, if they would take them, and landfill prices would increase.

It will take more than guaranteed loans to motivate someone to develop new energy uses for SRMs, deads, downers, etc. European countries have spent millions of dollars in researching new uses for these products, but they are still rendering them, and burning the end products. Some use tallow for biodiesel, but European renderers are subsidized. If grants are given, why doesn't USDA contact the Fats and Proteins Research Foundation?

23. What other innovative solutions could be explored?

The Fats and Proteins Research Foundation (FPRF) is allocating the majority of its research funds to finding other than feed uses for MBM. There are other uses for MBM, but it has to compete against cheap synthetic products. FPRF is working with Clemson University on nine projects toward the above goal. FPRF can use grant money, and I am sure Dr. Gary Pearl, the President of FPRF, will be contacting APHIS. A guaranteed loan has little or no value. FPRF needs million-dollar grants.

24. When and under what circumstances should the program transition from voluntary to mandatory?

As soon as possible.

25. What species should be covered, both initially and in the longer term? Specifically, should the initial emphasis be on cattle, or also cover other species? If so, which? Which species should be covered by the program when it is fully implemented? What priority should be given to including different species?

Cattle first, sheep second and swine third.

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

Print fact sheets and have local extension personnel hand out material at every county fair or public gathering. Mail fact sheets to U.S. households on regular basis in layman language. Have proper informed scientist appear on TV (Larry King Live, and etc.).

27. How can the Federal Government increase access to these materials?

Same as question 26.

28. Should FDA include exemptions to any news requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

Yes – Support the work mentioned earlier being conducted by FPRF and private industry to develop a quick and accurate test for ruminant proteins in ruminant rations. This is one IRT statement I agree with: “Through testing, inspection and enforcement” we can prevent ruminant products in ruminant feeds. Industry is making an exceptional effort to comply with FDA regulations. 99.5% compliance breaks the record. The other 0.5% need to be educated to the risks. We don’t need to change anything. Just stay with the 1997 ban and work with industry.

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

Solicit proposals for an accurate test for ruminant protein in feed. Much work is in progress, but a little assistance from FDA would speed up the process. I would predict within one year there will be a test for ruminant proteins in ruminant feeds, that FDA and renderers can use with confidence.

30. Do FDA’s existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in nonruminant animal feed (e.g., feed for horses, pigs, poultry, etc.) Notwithstanding that such materials have not been shown to pose a direct risk to nonruminant animals? More specifically, under FDA’s existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to nonruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

I am not a lawyer, but my answer is NO. I have suggested previously that we continue the same feeding requirements as written in 1997 feed ban. Countries that imported grossly discounted contaminated MBM from U.K. and France before 1987-88 are experiencing BSE problems. This material could have been transhipped several times. USDA, after a thorough investigation, believe none of this material was imported in U.S. I suggest renderers testing all dead animals and downers, and FSIS inspecting cows and bulls over 30 months of age. If we follow this procedure we will identify any additional infected Canadian or U.S. cattle.

NO. If there could be a cross-contamination problem, why haven’t we experienced it before now? If we test all animals over 30 months of age, we will identify any additional Canadian or U.S. infected cattle.

31. Are there other, related legal issues on which FDA should focus?

FDA should be concerned about the financial hardships their action could impose on all renderers, especially deadstock renderers. There has not been an indigenous case of BSE in U.S. The 1997 feed ban was an excellent rule. Any additional regulations would be difficult to defend in court, especially if no positive animals were discovered during USDA's enhanced testing period. I am not a lawyer, but I believe FDA has no legal right to impose additional regulations at this time.

32. What measures are necessary to prevent cross contamination between carcasses?

The question can be better answered by individuals more familiar with the slaughtering of animals.

33. In establishments that predominantly slaughter cattle 30 months of age and older, are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?

Same answer as Question 32. Has FSIS considered the quick test for cattle over 30 months of age for the next 2-3 years? This could eliminate the SRM removal problem, if after a few years no additional cases of BSE are identified. This could verify no proliferation in U.S. and Canada, plus calves fed ruminant protein before 1997 would have been slaughtered.

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?

Most informed individuals of the livestock industry consider the U.S. to be "BSE free," or at least "low-risk." Other countries, including "BSE-free" or "low risk," should only be exempted if their surveillance program is equivalent to the U.S.'s. Some countries have found that the easiest technique to become "BSE-free" and "scrapie free" is, don't look for it and bury all suspect animals behind the barn.

35. If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?

They test high-risk animals and same percentage of animals as the U.S. will be testing in the next 18 months. Meeting OIE standards is not enough.

36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

Station USDA personnel in country while enhanced testing is being conducted. Would not depend on OIE. U.S. should conduct our own evaluation of other country's procedures, in action.

Below are my conclusions:

1. There is no need to take samples for testing animals under 30 months of age.
2. There is no need for renderers to save SRMs from deadstock or downers under 30 months of age.
3. Renderers should take samples daily for quick-testing of all animals over 30 months of age, utilizing qualified and trained personnel. If we quick test all animals over 30 months of age, and they test negative, then there would be no need to remove SRMs from deads and downers. After the enhanced testing program, and we find none, or just a few, positives, we should continue *not* removing SRMs from deads or downers.
4. All SRMs procured by renderers should go into prohibited feed and be fed as we have been doing since 1997.
5. No change in the 1997 feed ban, except for the above suggested testing procedures.

NOTE:

I did not give specific data as to financial losses and tonnage, because NRA will be submitting a detailed report on these subjects from a third party analysis (INFORMA, Inc.).